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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|---------------|----------------------|------------------------------|------------------|--|
| 10/647,801 | 08/25/2003 | Dennis C. Liotta | 18085.105233CON1 (EMU 201 | 2351 | |
| 20786 | 7590 08/11 | 004 | EXAMINER | | |
| KING & SPALDING LLP 191 PEACHTREE STREET, N.E. | | | MAIER, L | MAIER, LEIGH C | |
| | GA 30303-1763 | • | ART UNIT | PAPER NUMBER | |
| • | | | 1623 | | |

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|--|--|--|--|--|--|--|
| Office Action Summary | | | | | | |
| | | 10/647,801 | LIOTTA ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | The MAII INC DATE of this accomplisation and | Leigh C. Maier | 1623 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| THE - External after - If the - If NC - Failu Any I | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1) | Responsive to communication(s) filed on | | | | | |
| 2a) <u></u> ☐ | This action is FINAL . 2b)⊠ This | action is non-final. | | | | |
| 3) | ,— | | | | | |
| Dispositi | on of Claims | | | | | |
| 5) 6) 7) | 4) Claim(s) 1-28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-28 are subject to restriction and/or election requirement. | | | | | |
| Applicati | on Papers | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) 🔲 . | 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11)[| The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | |
| Priority u | nder 35 U.S.C. § 119 | | | | | |
| a)[| Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document: 2. Certified copies of the priority document: 3. Copies of the certified copies of the priority application from the International Bureau ee the attached detailed Office action for a list | s have been received. s have been received in Application rity documents have been received (PCT Rule 17.2(a)). | on No d in this National Stage | | | |
| Attachment | (e) | | | | | |
| | e of References Cited (PTO-892) | 4) 🔲 Interview Summary (| DTO_413\ | | | |
| | e of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Dat | e | | | |
| | nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date | 5) Notice of Informal Pa | tent Application (PTO-152) | | | |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-8 and 11, drawn to sphingolipid derivates, classified in various classes and subclasses, depending on the definition of R².
- II. Claims 9, 10, 12-16, and 18-22, drawn to the treatment of proliferative disorders and modulating enzymes associated with said disorders, comprising administration of compounds of Group I, classified in class 514, various subclasses, depending on the definition of R².
- III. Claim 17, drawn to triggering the release of cytochrome c comprisingadministering a set of known compounds, classified in class 514, subclass 613+.
- IV. Claims 23-28, drawn to treatment/prevention of microbial infections, comprising administration of compounds of Group I, classified in class 514, various subclasses, depending on the definition of R².

The inventions are distinct, each from the other because of the following reasons:

Invention I is related to inventions II and IV as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of Group I can be used for the materially different methods recited in Groups II and IV.

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Although they comprise the administration of the same set of compounds, the search required for Group II is not required for Group IV, because the methods are drawn to different patient populations. Therefore, restriction for examination purposes as indicated is proper.

Invention III is unrelated to Inventions I, II, and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to the use of two non-overlapping sets of compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Claims 1, 2, 5-8 and 11 are generic to a plurality of disclosed patentably distinct species, depending on the definition of R². The definition of R² is recited in terms of chemical structure (such as peptide) or biological function (such as antibody). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, based on a generic definition of R², (e.g. carbohydrate; amino acid/peptide/polypeptide; phosphorylated group; hormone; antigen; etc.) even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://www.uspto.gov. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier Patent Examiner

Leigh C. Maier

August 6, 2004